

REMARKS

A Request for Continued Examination (RCE) and requisite fee have been submitted along with this Response. Since the Office Action was made final, the RCE was filed so that the Examiner would enter and consider the amendments and remarks of the present Response.

Status of All of the Claims

Below is the status of the claims in this application.

1. Claim(s) pending: 1, 2, 4-6, 8-25, 27-35.
2. Claim(s) canceled: 3, 7, and 26.
3. Claim(s) added: 32-35.
4. Claims withdrawn from consideration but not canceled: None.

It is believed that the above-identified new and amended claims are supported by the application as originally filed. For example, support for these claims can be at least found at pages 5, 10-14 of the specification and FIGS. 1-7 of the drawings.

Power of Attorney and Correspondence Address

As a housekeeping matter, it should be noted that a Power of Attorney to Prosecute Applications Before the USPTO for Roche Diagnostics Operations, Inc., a Statement Under 37 CFR 3.73(b) and a new Power of Attorney for this application were filed on November 21, 2006 in order to update the Power of Attorney and correspondence address to the current customer number (41577). As of to date, the correspondence address and power of attorney have not yet been updated to the 41577 customer number. It is believed that the requirements to update the Power of Attorney for this application were satisfied, but if additional documentation is required, the Examiner is invited to contact the undersigned by telephone to quickly resolve the issue.

Interview

The Applicants first wish to thank Examiner Winakur for the telephonic interview of May 3, 2007 concerning the above-identified application. At the Interview, proposed claim amendments similar to the amendments made above were presented. In particular, claims 1 and 25 have been amended to incorporate the features of dependent claims 7 and 26, respectively. As also proposed, claim 12 has been rewritten into independent form. Claims 1, 12, and 26 have been further amended in the manner as discussed at the Interview. For example, the claims have been amended to highlight the characteristics of the test volume, as was suggested by the Examiner during the Interview. At the Interview, the proposed amendments were discussed in view of the cited references, in particular U.S. Patent No. 5,553,616 to Ham et al.; U.S. Patent No. 6,370,406 to Wach et al.; U.S. Patent No. 6,584,335 to Haar et al.; and WO 02/07585 (Ward). The substantive remarks presented at the Interview have been provided below. Based on the indication from the Examiner that such amendments would distinguish the claims from current references of record, it is believed that the application is in condition for allowance.

Claim Objections

In item 6 of the Office Action, dependent claim 9 was objected to due to an informality. Claim 9 has been amended to correct the cited informality.

Claims Rejections – 35 USC §101

In item 7, claims 25-31 were “rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As noted on the Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility published on November 22, 2005 at 1300 OG 142, the Patent Office has the initial burden to establish that the claims fail to satisfy the subject matter eligibility requirement. It is submitted that the Patent Office has failed to meet this burden.

To be eligible for patent protection, the claimed invention as a whole must produce a “useful, concrete and tangible result.” Street Bank & Trust Co. v. Signature Financial Group Inc., 149 F. 3d 1368, 1373-74, 47 USPQ2d 1596, 1601-2 (Fed. Cir. 1998), see also, AT&T Corp. v. Excel Communications, Inc., 172 F.3d 1352, 50 USPQ2d 1447 (Fed. Cir. 1999). As discussed at the Interview, claim 25 clearly recites a useful, concrete and tangible result of “determining

concentration of analyte.” It should be recognized that accurately determined analyte levels are concrete, tangible and medically useful results for monitoring as well as for treating patients. It is therefore believed that claim 25 does not need to be amended so as to require the recitation of displaying results to a user. Based on the Examiner’s positive feedback from the Interview, it is believed that claims 25-31 satisfy the subject matter eligibility requirement of 35 U.S.C. §101.

Background

The inventors for the present application developed a unique and inventive reagent free analysis system for determining the concentration of analyte, which is well suited for continuous monitoring. Specifically, the inventors discovered that it was possible to determine the concentration of analytes, such as glucose, subcutaneously using light having a wavelength between 550 and 900 nm with Raman analysis. As discussed throughout the present application, background fluorescence is a major source of interference that inhibits Raman analysis. The inventors discovered a significant improvement in the signal to noise ratio (S/N) when the above-mentioned wavelength range was used for Raman analysis. As discussed in paragraphs [0029] (p. 8) and [0056] (p. 12) as well as elsewhere throughout the application, the inventors found that the interfering fluorescence is significantly reduced in this range whereby the S/N-ratio is improved. It was further found that interstitial fluid is particularly suited to Raman spectroscopy because interstitial fluid contains far fewer fluorescence molecules than blood (paragraph [0026], pp. 7-8). Moreover, as discussed in paragraph [0056] (p. 12) of the present application, there is a significant reduction in fluorescence interference when high molecular weight molecules are prevented by a semipermeable membrane from entering the test volume.

Independent Claim 1

As noted before, independent claim 1 has been amended to generally incorporate the features of claim 7 as well as to help clarify some recited features. In item 12 of the Office Action, claim 7 was “rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Ham et al. as applied to claims 1 and 25 above, and further in view of Haar et al. (PCT Application WO 99/07277) which corresponds to Haar et al. (US Patent 6,584,335 B1).” It is submitted that claim 1, as amended, is allowable over the references of record.

The seminal case directed to application of 35 U.S.C. §103 is Graham v. John Deere, 383 U.S. 1; 148 USPQ 459 (1966). From this case, four familiar factual inquiries have resulted: (1) determining the scope and contents of the prior art; (2) ascertaining the differences between the prior art and the claims in issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating evidence of secondary considerations. The first three are directed to the evaluation of prior art relative to the claims at issue, and the last is directed to evaluating evidence of secondary considerations. See, MPEP §2141. Recently, the U.S. Supreme has further clarified the Graham analysis in view of the Federal Circuit’s teaching, suggestion, or motivation test in KSR International Co. v. Teleflex Inc., 550 U. S. ____ , 82 USPQ2d 1385 (2007). “When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. ... a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art” KSR International, 550 U. S. ____ , 82 USPQ2d 1385, 1396 (2007, citations omitted). In KSR, however, the Supreme Court rejected a rigid application of the teaching, suggestion or motivation test (TSM), but instead, it adopted a flexible approach. “There is no necessary inconsistency between the idea underlying the TSM test and the Graham analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.” Id.

As explained at the Interview, the cited references disclose incompatible technologies such that one of ordinary skill in the relevant art would have not considered combining the cited references together in order to arrive at the recited combination of features. For example, Ward does not disclose a percutaneous (or in the skin) Raman sensor of the type recited in claim 25. Instead, Ward only refers to resonance Raman spectroscopy, and it does not concern conventional spontaneous spectroscopy. The resonance type Raman spectroscopy as taught by Ward is incompatible with the transmitted wavelengths recited in claim 1. Although on page 15, line 8, Ward mentions ultraviolet (UV) or near infrared range (NIR), it does not provide any examples of resonance Raman spectroscopy outside the “deep ultraviolet wavelength, i.e., 390 to 420 nm.” According to the inventors, resonance Raman spectroscopy for glucose is only practically possible in the UV range and is not possible at the NIR ranges recited in claim 1. Moreover, from the teachings of Ward, it is not expected that the exclusion of large molecules

(via a semi-permeable membrane) would reduce interfering fluorescence to such an extent that Raman spectroscopy analysis would be significantly improved. In particular, Ward teaches that NADH is a strongly fluorescent molecule, which is contained in interstitial fluid, and it has a low molecular weight (660). Thus, one would expect high fluorescence interference in interstitial fluid created by the low molecular weight NADH molecule. In other words, Ward's teachings are contrary to the surprising discovery that interfering fluorescence can be dramatically reduced by excluding high molecular weight molecules.

Ham describes a noninvasive system and does not disclose a percutaneous sensor of the type recited in claim 1. Furthermore, although it briefly mentions using a light beam at 780 nm, it teaches that a complicated neural network technique is required in order to filter out interference and obtain a useable signal. Thus, after reading Ham, one skilled in the art would likely not consider the wavelength taught by Ham as providing a fruitful avenue to pursue in order to reduce interference.

Haar concerns technology that is completely different from the Raman spectroscopy technique recited in claim 1. Specifically, Haar concerns Attenuated Total Reflection (ATR) spectroscopy (reflection within the optical fiber), and not Raman spectroscopy. Moreover, the ranges specified in Ward are outside those recited in claim 1. In particular, Haar teaches using a Mid Infrared Range (MIR) for detection purposes. In passing, Haar teaches jacketing the optical fiber with a semipermeable membrane and that the membrane has a "5,000 Da" molecular size cut-off in order to improve ATR spectroscopy (e.g., to reduce protein deposits on the light guide). Nothing suggests that the cut-off size has any particular importance for probe rejection, let alone in improving Raman spectroscopy. Considering that the cited references disclose incompatible technologies, there would have been no intrinsic or extrinsic reason for combining the references as contended in the Office Action. Based on the indication from the Interview that claim 1 as amended would be allowable over these references, it is submitted that claim 1 and its dependent claims are allowable over the references of record.

Independent Claim 12

As noted before, claim 12 has been rewritten into independent form as well as amended in order to help clarify some features. In item 14 of the Office Action, claim 12 was “rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Ham et al. as applied to claims 1 and 25 above, and further in view of Wach et al. (US Patent 6,370,406). However, the cited references fail to disclose all of the features as recited in claim 12. As discussed at the Interview, Wach fails to disclose or suggest “wherein the sensor head includes a reflective surface positioned around the test volume to reflect the Raman-scattered components of the secondary light towards the light receiving surface of the detection light guide” as is recited in claim 12 (emphasis added). The other remaining references fail to remedy this missing feature. For these and other reasons, it is submitted that claim 12 and its dependent claims are allowable over the references of record.

Independent Claim 25

As noted before, claim 25 has been amended to incorporate the features of dependent claim 26. In item 12 of the Office Action, claim 26 was “rejected under 35 U.S.C. 103(a) as being unpatentable over Ward et al. in view of Ham et al. as applied to claims 1 and 25 above, and further in view of Haar et al. (PCT Application WO 99/07277) which corresponds to Haar et al. (US Patent 6,584,335 B1).” It is submitted that claim 25, as amended, is allowable over the references of record. As discussed above for claim 1, Ward, Ham, and Haar describe incompatible technologies such that there would have been no intrinsic or extrinsic reason to combine these references to arrive at the combination of features recited in claim 25. Considering the positive feedback received regarding claim 25 from the Interview, it is believed that claim 25 and its dependent claims are allowable over the references of record.

Information Disclosure Statement

As a housekeeping matter, it should be noted that an Information Disclosure Statement (IDS) has been submitted with this response. This IDS was submitted in order to cite the references identified by the Examiner during the Interview that might be of some relevance. The Applicants kindly request that the Examiner returns an initialed copy of the IDS form with the next communication from the Patent Office.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion.

In view of the above amendments and remarks, it is submitted that the present application is now in condition for allowance, and the Examiner is requested to pass the case to issue. If the Examiner should have any comments or suggestions to help speed the prosecution of this application, the Examiner is requested to contact the undersigned representative by telephone.

Respectfully submitted,

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